

PATENT COOPERATION TREATY


PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 07 NOV 2005

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|--|--|---|--|----------------------|
| Applicant's or agent's file reference BARAHY4345 | | FOR FURTHER ACTION | | See Form PCT/PEA/416 |
| International application No. PCT/GB2004/004817 | | International filing date (day/month/year) 17.11.2004 | Priority date (day/month/year) 11.12.2003 | |
| International Patent Classification (IPC) or national classification and IPC C12Q1/00, C12N9/06 | | | | |
| Applicant UNIVERSITY OF WALES, BANGOR et al. | | | | |
| <p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p> | | | | |
| <p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p> | | | | |
| Date of submission of the demand 28.05.2005 | | Date of completion of this report 04.11.2005 | | |
| Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465 | | Authorized Officer Thiele, U Telephone No. +49 89 2399- | | |



**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/GB2004/004817

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4)
 - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-30 as originally filed

Sequence listings part of the description, Pages

1-11 as originally filed

Claims, Numbers

1-27 as originally filed

Drawings, Sheets

1/13-13/13 as originally filed

☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

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**INTERNATIONAL PRELIMINARY REPORT
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Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | |
| | No: Claims | 1-27 |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-27 |
| Industrial applicability (IA) | Yes: Claims | 1-27 |
| | No: Claims | |

2. Citations and explanations (Rule 70.7):

see separate sheet

**INTERNATIONAL PRELIMINARY REPORT
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Supplemental Box relating to Sequence Listing

Continuation of Box I, item 2:

1. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this report has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment on
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional observations, if necessary:

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Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1) Reference is made to the following documents:

- D1: C.D. GWENIN ET AL.: "The development of a novel amperometric biosensor for the detection of nitro explosives" ABSTRACTS OF THE ANNUAL MEETING OF THE INTERNATIONAL SOCIETY OF BIOCHEMISTRY, [Online] vol. 55, 19 September 2004 (2004-09-19), page 1, XP002314074 Retrieved from the Internet: URL:<http://www.google.de/search?q=cache:MNxdOHpOAUgJ:www.isechemistry.gr/showabs.php%3FID%3DS4FP118+kalaji+nitroreductases&hl=de> [retrieved on 2005-01-05]
- D2: CHRIS GWENIN: "Poster 50: The Development of an Amperometric Enzyme Sensor for the Detection of Explosives" POSTERS OF THE 2003 YOUNGER EUROPEAN CHEMISTS' CONFERENCE, [Online] 26 August 2003 (2003-08-26), pages 1-19, XP002314075 GRENOBLE 2003 Retrieved from the Internet: URL:<http://www.setforeurope.org/grenoble/New%20Folder/posters.htm> [retrieved on 2005-01-05]
- D3: DATABASE Geneseq [Online] 27 February 1996 (1996-02-27), "E. coli nitro reductase gene." XP002314077 retrieved from EBI accession no. GSN:AAQ92891 Database accession no. AAQ92891
- D4: DATABASE EMBL [Online] 2 October 2001 (2001-10-02), "Pseudomonas putida KT2440 flavoprotein (ecd) gene, complete cds." XP002314078 retrieved from EBI accession no. EM_PRO:AF417209 Database accession no. AF417209
- D5: DATABASE EMBL [Online] 21 August 2002 (2002-08-21), "Pseudomonas putida oxygen-insensitive NADPH nitroreductase (pnrA) gene, complete cds." XP002314079 retrieved from EBI accession no. EM_PRO:AF532911 Database accession no. AF532911
- D6: X. REN ET AL.: "A new type of reusable piezoimmunosensor fabricated by a recombinant IgG-binding protein" ANALYST, [Online] vol. 125, 24 February 2000 (2000-02-24), pages 669-671, XP002314076 Retrieved from the Internet: URL:<http://pubs.rsc.org/ej/AN/2000/a909736h.pdf>

D7: GB-A-2 332 432 (SECR DEFENCE) 23 June 1999 (1999-06-23)

- 2) The present application would appear not to meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1 - 27 is not new in the sense of Article 33(2) PCT.

One of the present inventors is listed as presenter of a poster with the title "The development of an amperometric enzyme sensor for the detection of explosives" (cf. D1). The work is described as the "[d]evelopment of an in-situ electrochemical method for the detection of trace level vapours from nitroaromatic compounds, as in explosives".

It appears more likely than not on the balance of probabilities that the subject-matter of all pending claims has been disclosed at the Third Younger European Chemist's Conference prior to the priority date of the present application.

It would appear from a reading of the instant application that only the particular enzymes in connection with the Cysteine tags and the particular immobilisation on a noble metal layer can solve the problem of detection of trace level vapours from nitroaromatic compounds, as in explosives. It is also evident from the present application that it is not reasonable to predict that enzymes other than the ones encoded by SEQ IDs 1 and 2 will detect a broad range of nitrates, or nitrates at low concentration levels (see i.a. page 4, paragraph 3).

- 3) The present application would further appear not to meet the criteria of Article 33(1) PCT, because the subject-matter of claim 25 is not new in the sense of Article 33(2) PCT vis-à-vis D3 - D5.

D3 discloses present SEQ ID 1, and D4 and D5 anticipate SEQ ID 2.

- 4) Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D2 - D5 is not mentioned in the description, nor are these documents identified therein.